Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Chronic pain disorder medical treatment guideline.

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Chronic pain disorder medical treatment guideline. Denver (CO): Colorado Division of Workers' Compensation; 2017 Nov 30. 178 p.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Colorado Division of Workers' Compensation. Chronic pain disorder medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2011 Dec 27. 110 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▯	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▯	Evidence Summary Supporting Recommendations
▮▮▮▯▯	Rating the Strength of Recommendations
▮▮▮▮▯	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This summary includes the treatment recommendations of the guideline. See the original guideline document for additional information on initial evaluation and diagnostic procedures for patients with chronic pain disorders and for further descriptions of the therapies discussed below.

The grades of recommendations (Some, Good, Strong) are defined at the end of the Major Recommendations field.

Therapeutic Procedures—Non-operative

Non-operative therapeutic rehabilitation is applied to patients with chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity, complexity of the problem, and anticipated therapeutic effect. Treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

All treatment plans begin with shared decision making with the patients. Before initiation of any therapeutic procedure, an authorized treating physician, employer and insurer must consider these important issues in the care of the injured worker:

Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" below for detailed information.

Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies, or consultations should be pursued.

Continued treatment should be monitored using objective measures such as:

- Return-to-work or maintaining work status
- Fewer restrictions at work or performing activities of daily living (ADL)
- Decrease in usage of medications related to the work injury
- Measurable functional gains, such as increased range-of-motion, documented increase in strength, increased ability to stand, sit or lift, or patient completed functional evaluation

Clinicians should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms

Psychological or psychosocial screening should be performed on all chronic pain patients.

Acupuncture

Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute pain for patients who cannot tolerate nonsteroidal anti-inflammatory drugs (NSAIDs) or other medications.

Evidence Statements Regarding Acupuncture

Good Evidence

The small therapeutic effects of needle acupuncture, active laser acupuncture, and sham acupuncture for reducing pain or improving function among patients older than 50 years with moderate to severe chronic knee pain from symptoms of osteoarthritis are due to non-specific effects similar to placebo (Design: Negative randomized clinical trial).

Acupuncture is effective in the treatment of low back pain in patients with positive expectations of acupuncture (Design: Randomized clinical trial).

Acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, but true and sham acupuncture are likely to be equally effective (Design: Randomized clinical trial).

Some Evidence

In the setting of chronic joint pain arising from aromatase inhibitor treatment of non-metastatic breast cancer, the symptomatic relief from acupuncture is strongly influenced by the expectations with which patients approach treatment, and a patient who expects significant benefits from acupuncture is more likely to derive benefits from sham acupuncture than a patient with low expectations is to derive benefits from real acupuncture. On average, real and sham acupuncture do not lead to significantly different symptom responses, but different treatment expectations do lead to different symptom responses (Design: Randomized clinical trial).

Acupuncture is better than no acupuncture for axial chronic low back pain (Design: Randomized clinical trial).

Summary of Evidence Regarding Acupuncture

Based on the multiple studies with good and some evidence listed above, there is strong evidence that true or sham acupuncture may be useful for chronic low back pain in patients with high expectations, and it should be used accordingly.

See the original guideline document for indications, time to produce effect, frequency, and optimum and maximum duration.

Biofeedback

Evidence Statements Regarding Biofeedback

Good Evidence

Biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain (Design: Meta-analysis of controlled clinical trials).
Cognitive behavioral therapy, but not behavioral therapy e.g., biofeedback, shows weak to small effects in reducing pain and small effects on improving disability, mood, and catastrophizing in patients with chronic pain (Design: Meta-analysis of randomized clinical trials favoring cognitive behavioral therapy over biofeedback).

See the original guideline document for indications, types of biofeedback, time to produce effect, frequency, and optimum and maximum duration.

Complementary Medicine

Evidence Statements Regarding Complementary Medicine

Some Evidence

A 10-week Tai Chi program was effective for improving pain symptoms and disability compared with usual care controls for those who have chronic low back pain symptoms (Design: Assessor single-blind randomized controlled trial).

See the original guideline document for types of complementary medicine, time to produce effect, frequency, and optimum duration.

Direct Cortical Stimulation

There are several types of cortical stimulation to relieve pain. All of these are undergoing further investigation and are considered experimental at this time. The limited studies available do not allow translation to the workers' compensation chronic pain population. An invasive option is implantation in the epidural motor cortex. Given the invasive nature and lack of evidence applying to the working population, direct cortical stimulation is *not recommended*.

Disturbances of Sleep

Evidence Statements Regarding Disturbance of Sleep

Some Evidence

Group cognitive behavioral therapy reduces the severity and daytime consequences of insomnia for at least six months (Design: Randomized clinical trial).
Behavioral modification, such as patient education and group or individual counseling with cognitive behavioral therapy, can be effective in reversing the effects of insomnia (Design: Randomized clinical trial).
Ramelteon, while producing a small amount of reduction in sleep latency, does not appreciably increase total sleep time or daytime function (Design: Randomized clinical trial).
A dietary supplement containing melatonin, magnesium, and zinc, conveyed in pear pulp, taken 1 hour before bedtime, results in significantly better quality of sleep and quality of life than a placebo treatment in long-term care facility residents aged 70 and older with primary insomnia (Design: Double-blind placebo controlled randomized clinical trial).
The following medications exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin (Design: Randomized clinical trial).

Summary of Evidence Regarding Disturbance of Sleep

Based on the multiple studies with some evidence listed above, there is good evidence supporting the use of cognitive behavioral therapy for sleep disturbances.

Education/Informed/Shared Decision Making

Evidence Statements Regarding Education/Informed Decision Making

Some Evidence

Information provided only by video is not sufficient education (Design: Prospective randomized controlled trial).

See original guideline document for time to produce effect and frequency.

Injections—Spinal Therapeutic

Intradiscal Steroid Injection

There is some evidence that intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain; therefore, they are *not recommended*. Intradiscal injections of other substances such as bone marrow, stem cells, are *not recommended* at this time due to lack of evidence and possible complications.

Transforaminal Injection with Etanercept

Transforaminal injection with etanercept is *not recommended* due to the results of a study which showed no advantage over steroids or saline injections.

Evidence Statements Regarding Therapeutic Spinal Injections and Steroid Associated Issues

Strong Evidence

Epidural steroid injections (ESIs) have a small average short-term benefit for leg pain and disability for those with sciatica (Design: Meta-analysis of randomized clinical trials).
ESIs do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy) (Design: Meta-analysis of randomized clinical trials).
ESIs have no short-term or long-term benefit for low back pain (Design: Meta-analysis of randomized clinical trials).

Good Evidence

The addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability (Design: Randomized clinical trials).
There are no significant differences between epidural injections with corticosteroid plus local anesthetic versus local anesthetic alone in patients with symptomatic spinal stenosis. However, there are measureable differences with respect to morning cortisol levels at 3 and 6 weeks after the injection, suggesting that the corticosteroid injection is capable of inducing suppression of the hypothalamic-pituitary-adrenal axis (Design: Randomized clinical trial).

Some Evidence

The addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. The benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given (Design: Randomized clinical trial).
After 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the

patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting (Design: Randomized clinical trial).
An intra-articular injection of 80 mg of methylprednisolone acetate into the knee has about a 25% probability of suppressing the adrenal gland response to exogenous adrenocortocotrophic hormone (ACTH) for 4 or more weeks after injection, but complete recovery of the adrenal response is seen by week 8 after injection (Design: Randomized clinical trial).
Patients who smoke respond less well to non-operative spine care, and quitting smoking results in greater improvement (Design: Prospective cohort study).
Translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic (Design: Randomized clinical trial).
Intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain (Design: Randomized clinical trial).

Evidence Against

Good Evidence

There is good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain (Design: Systematic review of randomized clinical trials).

See original guideline document for maximum duration and a list of types of injections.

Injections—Other (Including Radio Frequency)

Botulinum Toxin Injections

There is a lack of adequate evidence supporting the use of these injections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is *not recommended* for use for low back pain or other myofascial trigger points.

Evidence Statements Regarding Botulinum Toxin Injections for Cervical Dystonia

Strong Evidence

Botulinum toxin A has objective and asymptomatic benefits over placebo for cervical dystonia (Design: Meta-analysis of randomized clinical trials).

Good Evidence

A single injection of botulinum toxin type B is more effective than placebo in alleviating the severity and pain of idiopathic cervical dystonia. The duration of effect of botulinum toxin type B is not certain but appears to be approximately 12 to 18 weeks (Design: Meta-analysis of randomized clinical trials).

Evidence Statements regarding Botulinum Toxin Injections for Piriformis Syndrome

Some Evidence

There is some evidence to support injections for electromyographically proven piriformis syndrome (Design: Randomized clinical trial).

See the original guideline document for indications, complications, time to produce effect, frequency, and optimum and maximum duration.

Epiduroscopy and Epidural Lysis of Adhesions

Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood

of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epiduroscopy, or mechanical lysis, is *not recommended*.

Epiduroscopy-directed steroid injections are also *not recommended* because there is no evidence to support an advantage in using an epiduroscope with steroid injections.

Prolotherapy

The use of prolotherapy for low back pain is generally *not recommended*, as the majority of patients with sacroiliac (SI) joint dysfunction will do well with a combination of active therapy and manipulation and not require prolotherapy. However, it may be used in select patients. Prolotherapy is *not recommended* for other non-specific back pain.

Evidence Statements Regarding Prolotherapy

Good Evidence

Prolotherapy alone is not an effective treatment for chronic low back pain (Design: Systematic reviews of controlled clinical trials).

Some Evidence

Prolotherapy of the SI joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear; however, all injections were done under fluoroscopic guidance (Design: Randomized clinical trial).

Radio Frequency (RF) Ablation—Dorsal Nerve Root Ganglion

Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this treatment is *not recommended*.

Radio Frequency Ablation—Genicular Nerves: Neurotomy

There is currently inadequate evidence to support radiofrequency neurotomy for knee osteoarthritis failing conservative therapy.

Radio Frequency Denervation—Medical Branch Neurotomy/Facet Rhizotomy

Cooled radiofrequency is generally *not recommended* due to current lack of evidence. This procedure is *not recommended* for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves or 2 facet levels unilateral or bilateral.

Evidence Statements Regarding Radio Frequency Denervation - Medial Branch Neurotomy/Facet Rhizotomy

Good Evidence

For the lumbar spine, carefully selected patients who had 80% relief with medial branch controlled blinded blocks and then had RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those who had sham procedures. Pain relief was defined as one hour of 80% relief from the lidocaine injection and two hours of 80% relief with bupivacaine (Design: Randomized clinical trials).

See the original guideline document for indications, complications, post-procedure therapy, and requirements for repeat radiofrequency medial branch neurotomy.

Radio Frequency Denervation—Sacroiliac Joint Cooled

Evidence Statements Regarding Radio Frequency Denervation—Sacroiliac Joint Cooled

Good Evidence

Cooled RF neurotomy performed in a highly selected population results in better pain relief and functional gains than a sham procedure. The benefits persisted for 9 months. Approximate half of the patients had

benefits initially, and approximately half of those reported the pain was completely relieved (Design: Randomized clinical trial).

See the original guideline document for indications, complications, post-procedure therapy, and requirements for repeat radiofrequency SI joint neurotomy.

Transdiscal Biacuplasty

It is *not recommended* due to lack of published data demonstrating effectiveness.

Trigger Point Injections

Trigger point injections are generally accepted treatments.

See the original guideline document for indications, complications, time to produce effect, frequency, and optimum/maximum duration.

Interdisciplinary Rehabilitation Program

Evidence Statements Regarding Interdisciplinary Rehabilitation Programs

Good Evidence

> Interdisciplinary programs that include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability (Design: Cluster randomized trial, randomized clinical trial).
> Multidisciplinary rehabilitation (physical therapy and either psychological, social, or occupational therapy) shows small effects in reducing pain and improving disability compared to usual care, and multidisciplinary biopsychosocial rehabilitation is more effective than physical treatment for disability improvement after 12 months of treatment in patients with chronic low back pain. Patients with a significant psychosocial impact are most likely to benefit (Design: Meta-analyses of randomized clinical trials).
> Exercise alone or as part of a multidisciplinary program results in decreased disability for workers with non-acute low back pain (Design: Meta-analyses of randomized clinical trials).

Some Evidence

> Telephone-delivered collaborative care management intervention for primary care veteran patients produced clinically meaningful improvements in pain at 12-month follow-up compared with usual care by increasing non-opioid analgesic medications and without changing opioid usage for the management of chronic musculoskeletal pain. The management was directed by nurse case managers. Because the control group was usual care rather than an attention control, the non-specific effects of attention received in the intervention group could have contributed to the effectiveness of the intervention. If an attention control had been used as the control group, the effect size observed for improvement in pain in the intervention group may have been smaller. It is unknown how successful this would be with injured workers (Design: Single-blind randomized clinical trial).
> An integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain (Design: Randomized clinical trial).

See the original guideline document for time to produce effect, frequency, and optimum and maximum duration for pain rehabilitation, occupational rehabilitation, and informal interdisciplinary rehabilitation program.

Medications and Medical Management

Evidence Statements Regarding Medication Management

Some Evidence

In the setting of uncomplicated low back pain lasting longer than 3 months, patients who were willing to participate in a trial of capsules clearly labelled as placebo experienced short-term reductions in pain and disability after the principles of the placebo effect had been explained to them (Design: Randomized clinical trial).

The following drug classes are listed in alphabetical order, not in order of suggested use, which is outlined in the original guideline document for neuropathic pain. See the original guideline document for specific information about individual drugs, including indications, contraindications, dosing and time to therapeutic effect, major side effects, drug interactions, and laboratory monitoring.

- Alpha-acting agents
- Anticonvulsants
- Antidepressants
- Cannabinoid products
- Hypnotics and sedatives
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Opioids
- Post-operative pain management
- Skeletal muscle relaxants
- Smoking cessation medications and treatment
- Topical drug delivery
- Other agents

Anticonvulsants

Evidence Statements Regarding Anticonvulsants: Gabapentin (Fanatrex, Gabarone, Gralise, Horizant, Neurontin)

Strong Evidence

- Gabapentin is more effective than placebo in the relief of painful diabetic neuropathy and post-herpetic neuralgia (Design: Meta-analysis of randomized clinical trials).
- Gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients (Design: Randomized clinical trial, meta-analysis of randomized trials).

Good Evidence

Gabapentin is not superior to amitriptyline (Design: Randomized crossover trial, meta-analysis of randomized trials).

Some Evidence

- Gabapentin may benefit some patients with post-traumatic neuropathic pain (Design: Randomized clinical trial).
- Nortriptyline (Aventyl, Pamelor) and gabapentin are equally effective for pain relief of post-herpetic neuralgia (Design: Randomized clinical trial).
- The combination of gabapentin and morphine may allow lower doses with greater analgesic effect than the drugs given separately (Design: Randomized crossover trial).
- A combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug (Design: Randomized crossover trial).

Evidence Statements Regarding Anticonvulsants: Pregabalin (Lyrica)

Strong Evidence

In the setting of painful diabetic neuropathy, pregabalin as a stand-alone treatment is more effective

than placebo in producing a 50% pain reduction, but this goal is realized in only 36% of patients treated with pregabalin compared with 24% of patients treated with placebo (Design: Meta-analysis of randomized clinical trials).

Good Evidence

When pregabalin is compared with other first line medications for the treatment of neuropathic pain and diabetic peripheral neuropathy, such as amitriptyline and duloxetine, it is not superior to these medications. Additionally, amitriptyline was found more effective compared to pregabalin for reducing pain scores and disability. Side effects were similar for the two medications (Design: Randomized clinical trial, open label parallel randomized clinical trial, randomized clinical trial).

Some Evidence

Pregabalin may be effective in treating neuropathic pain due to spinal cord injury (Design: Randomized parallel group clinical trial).
Duloxetine, pregabalin, and amitriptyline exert different effects with respect to sleep variables. Total sleep time and REM sleep duration are likely to be greater with pregabalin than with duloxetine or amitriptyline. However, pregabalin is likely to lead to dizziness and fatigue more frequently than the other drugs, and oxygen desaturation during sleep also appears to be greater with pregabalin (Design: Randomized clinical trial).

Evidence Statements Regarding Anticonvulsants: Topiramate (Topamax, Topiragen)

Good Evidence

Topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain (Design: Randomized crossover trial, randomized clinical trials).

Evidence Statements Regarding Anticonvulsants: Carbamazepine

Good Evidence

Rapid dose titration produces side-effects greater than the analgesic benefits (Design: Randomized clinical trials).

Antidepressants

Evidence Statement Regarding Antidepressants: Tricyclics and older agents (e.g., amitriptyline, nortriptyline, doxepin [Adapin, Silenor, Sinequan], desipramine [Norpramin, Pertofrane], imipramine [Tofranil], trazodone [Desyrel, Oleptro])

Good Evidence

Gabapentin is not superior to amitriptyline (Design: Randomized crossover trial, meta-analysis of randomized trials).

Some Evidence

In the setting of chronic low back pain with or without radiculopathy, amitriptyline is more effective than pregabalin at reducing pain and disability after 14 weeks of treatment (Design: Open label parallel randomized clinical trial).
In the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline (Design: Crossover randomized trial).
A combination of some gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug, without increasing side effects of either drug (Design: Randomized crossover trial).

Evidence Statements Regarding Antidepressants: Selective Serotonin Nor-epinephrine Reuptake Inhibitor (SSNRI)/Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI)

Strong Evidence

Duloxetine monotherapy is more effective than placebo in relieving the pain of diabetic peripheral neuropathy; however, monotherapy leads to a 50% pain reduction in only half of patients who receive a therapeutic dose (Design: Meta-analysis of randomized clinical trials).

Good Evidence

In patients with painful diabetic neuropathy who have not had good responses to monotherapy with 60 mg of duloxetine or 300 mg of pregabalin, a clinically important benefit can be achieved by either of two strategies: doubling the dose of either drug, or combining both drugs at the same dose. It is likely that the strategy of combining the two drugs at doses of 60 and 300 mg respectively is more beneficial overall (Design: Randomized clinical trial).

Cannabinoid Products

At the time of writing, marijuana use is illegal under federal law and *cannot be recommended* for use in this guideline. The Colorado Constitution also states that insurers are not required to pay for marijuana.

The following pharmaceutical cannabinoid products are *generally not recommended for pain* but providers may choose to prescribe them off-label:

Dronabinal (Marinol)
Nabilone (Cesamet)
Nabiximols (Sativex)

Evidence Statements Regarding Cannabinoid Products

Good Evidence

Cannabinoids containing tetrahydrocannabinol (THC) are associated with a small to moderate improvement in chronic pain compared to placebo; however, the dosage needed to produce an analgesic effect is undefined and uncertain (Design: Systematic review and meta-analysis of randomized clinical trials).

Some Evidence

Nabiximols can modestly decrease peripheral neuropathic pain with allodynia in some patients who were concomitantly treated with opioids or anticonvulsants; however, the drop-out rate for those who continued the medication longer term was high (Design: Randomized clinical trial).

Hypnotics and Sedatives

Benzodiazepine-based hypnotics include temazepam (Restoril, Temazepam, Gelthix), triazolam (Halcion), and flurazepam (Dalmane). None are recommended because of habit-forming potential, withdrawal symptoms, and sedating side effects. Flurazepam has an active metabolite with a very long half-life, resulting in drug accumulation and next-day somnolence. These medications are *not recommended* for use in the working populations.

Evidence Statements Regarding Hypnotics and Sedatives

Some Evidence

Zolpidem does not appreciably enhance the effectiveness of cognitive behavioral therapy (Design: Randomized clinical trial).

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Chronic use of NSAIDs is generally *not recommended* due to increased risk of cardiovascular events and

gastrointestinal (GI) bleeding.

Evidence Statements Regarding NSAIDs

Good Evidence

> Celecoxib in a dose of 200 mg per day, administered over a long period, does not have a worse cardiovascular risk profile than naproxen at a dose of up to 1000 mg per day or ibuprofen at a dose of up to 2400 mg per day (Design: Randomized noninferiority trial).
> Celecoxib has a more favorable safety profile than ibuprofen or naproxen with respect to serious GI adverse events, and it has a more favorable safety profile than ibuprofen with respect to renal adverse events (Design: Randomized noninferiority trial).

Some Evidence

Topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs (Design: Meta-analysis of randomized clinical trials).

Opioids

Evidence Statements Regarding Effectiveness and Side Effects of Opioids

Strong Evidence

> In the setting of chronic nonspecific low back pain, the short and intermediate term reduction in pain intensity of opioids, compared with placebo, falls short of a clinically important level of effectiveness (Design: Systematic review and meta-analysis).
> Adverse events such as constipation, dizziness, and drowsiness are more frequent with opioids than with placebo (Design: Systematic review and meta-analysis).

Good Evidence

> Opioids are more efficient than placebo in reducing neuropathic pain by clinically significant amounts (Design: Systematic review and meta-analysis of randomized clinical trials).
> Opioids produce significantly more adverse effects than placebo such as constipation, drowsiness, dizziness, nausea, and vomiting (Design: Systematic review and meta-analysis of randomized clinical trials).
> Naloxegol can alleviate opioid induced constipation and 12.5 mg starting dose has an acceptable side effect profile (Design: Two identical and simultaneous multicenter randomized double-blind studies).

Some Evidence

In the setting of chronic low back pain with disc pathology, a high degree of anxiety or depressive symptomatology is associated with relatively less pain relief in spite of higher opioid dosage than when these symptoms are absent (Design: Prospective cohort study).

Evidence Statements Regarding Opioids and Adverse Events

Good Evidence

> In generally healthy patients with chronic musculoskeletal pain, treatment with long-acting opioids, compared to treatments with anticonvulsants or antidepressants, is associated with an increased risk of death of approximately 69%, most of which arises from non-overdose causes, principally cardiovascular in nature. The excess cardiovascular mortality principally occurs in the first 180 days from starting opioid treatment (Design: Retrospective matched cohort study).
> Prescription opioids in excess of 200 morphine milligram equivalents (MME) average daily doses are associated with a near tripling of the risk of opioid-related death, compared to average daily doses of 20 MME. Average daily doses of 100-200 mg and doses of 50-99 mg per day may be associated with a doubling of mortality risk, but these risk estimates need to be replicated with larger studies

(Design: Nested case-control study with incidence density sampling).

Some Evidence

Compared to an opioid dose under 20 MME per day, a dose of 20-50 mg nearly doubles the risk of death, a dose of 50 to 100 mg may increase the risk more than fourfold, and a dose greater than 100 mg per day may increase the risk as much as sevenfold. However, the absolute risk of fatal overdose of in chronic pain patients is fairly low, and may be as low as 0.04% (Design: Case-cohort study).

Summary of Evidence Regarding Opioids and Adverse Events

Based on the studies with good evidence and some evidence listed above, there is strong evidence that any dose above 50 MME per day is associated with a higher risk of death and 100 mg or greater appears to significantly increase the risk.

Types of opioids:

Buprenorphine (various formulations) is *not recommended* for most chronic pain patients due to methods of administration, reports of euphoria in some patients, and lack of proof for improved efficacy in comparison with other opioids.
Codeine with acetaminophen
Fentanyl (Actiq, Duragesic, Fentora, Sublimaze) is *not recommended* for use with musculoskeletal chronic pain patients.
Meperidine (Demerol) is *not recommended* for chronic pain.
Methadone
Morphine
Oxycodone and hydromorphone
Propoxyphene (Darvon, Davon-N, PP-Cap)
Tapentadol (Nucynta) is *not recommended* as a first line opioid for chronic, subacute, or acute pain due to the cost and lack of superiority over other analgesics.
Tramadol (Rybix, Ryzolt, Ultram) is *not recommended* in those with prior opioid addiction.

Transdermal medication use, other than buprenorphine, is generally *not recommended*.

There is some evidence that dextromethorphan does not potentiate the effect of morphine opioids and therefore is *not recommended* to be used with opioids.

Evidence Statements Regarding Choice of Opioids, Indications, and Recommendations for Use

Strong Evidence

In patients being treated with opioid agonists for heroin addiction, methadone is more successful than buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine (Design: Meta-analysis of randomized clinical trials).
Buprenorphine is superior to placebo with respect to retention in treatment (Design: Meta-analysis of randomized clinical trials).

Good Evidence

Buprenorphine is superior to placebo with respect to positive urine testing for opiates (Design: Meta-analysis of randomized clinical trials).
In the setting of new onset chronic noncancer pain, there is a clinically important relationship between opioid prescription and subsequent opioid use disorder. Compared to no opioid use, short-term opioid use approximately triples the risk of opioid use disorder in the next 18 months. Use of opioids for over 90 days is associated with very pronounced increased risks of the subsequent development of an opioid use disorder, which may be as much as one hundredfold when doses greater than 120 MME are taken for more than 90 days. The absolute risk of these disorders is very uncertain but is likely to be greater than 6.1% for long duration treatment with a high opioid dose

(Design: Retrospective cohort study using claims data from a large health care database).
Extended release tapentadol is more effective than placebo and comparable to oxycodone. The percent of patients who achieved 50% or greater pain relief was: placebo, 18.9%, tapentadol, 27.0%, and oxycodone, 23.3% (Design: Randomized clinical trial).
Transdermal buprenorphine is noninferior to oral tramadol in the treatment of moderate to severe musculoskeletal pain arising from conditions like osteoarthritis and low back pain. The population of patients for whom it is more appropriate than tramadol is not established but would need to be determined on an individual patient basis if there are clear reasons not to use oral tramadol (Design: Phase III noninferiority trial).
Transdermal fentanyl and transdermal buprenorphine are similar with respect to analgesia and sleep quality, and they are similar with respect to some common adverse effects such as constipation and discontinuation due to lack of effect. However, buprenorphine probably causes significantly less nausea than fentanyl, and it probably carries a lower risk of treatment discontinuation due to adverse events. It is also likely that both transdermal medications cause less constipation than oral morphine (Design: Network meta-analysis of randomized clinical trials).
In the setting of common low back injuries, when baseline pain and injury severity are taken into account, a prescription for more than seven days of opioids in the first 6 weeks is associated with an approximate doubling of disability one year after the injury (Design: Prospective cohort study).

Some Evidence

Long-acting oxycodone (Dazidox, Endocodone, ETH-oxydose, Oxycontin, Oxyfast, OxyIR, Percolone, Roxicodone) and oxymorphone have equal analgesic effects and side effects, although the milligram dose of oxymorphone (Opana) is half that of oxycodone (Design: Randomized clinical trial).
Extended release hydrocodone has a small and clinically unimportant advantage over placebo for relief of chronic low back pain among patients who are able to tolerate the drug and 40% of patients who begin taking the drug do not attain a dose which provides pain relief without unacceptable adverse effects. Hydrocodone extended release (ER) does not appear to improve function in comparison with placebo (Design: Randomized trial with a screening period of 7-14 days followed by an open-label titration period of up to 6 weeks followed by a double blind treatment period of up to 12 weeks).
In the setting of neuropathic pain, a combination of morphine plus nortriptyline produces better pain relief than either monotherapy alone, but morphine monotherapy is not superior to nortriptyline monotherapy, and it is possible that it is actually less effective than nortriptyline (Design: Crossover randomized trial).
Tapentadol can reduce pain to a moderate degree in diabetic neuropathy, average difference 1.4/10 pain scale, with tolerable adverse effects (Design: Randomized clinical trial).
Tapentadol causes less constipation than oxycodone (Design: Meta-analysis of randomized clinical trials).
Dextromethorphan does not potentiate the effect of morphine opioids and therefore is *not recommended* to be used with opioids (Design: Three randomized clinical trials).
Tramadol alleviates neuropathic pain following spinal cord injury (Design: Randomized clinical trial).
Tramadol yields a short-term analgesic response of little clinical importance relative to placebo in postherpetic neuralgia which has been symptomatic for approximately 6 months (Design: Randomized clinical trial).

Post-Operative Pain Management

Ketamine is *not recommended* as a first line medication for most patients.

Skeletal Muscle Relaxants

Chronic use of benzodiazepines or any muscle relaxant is *not recommended* due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on chronic opioids due to respiratory depression.

Smoking Cessation Medications and Treatment

Evidence Statements Regarding Smoking Cessation Medications and Treatment

Some Evidence

> Among adults motivated to quit smoking, 12 weeks of open-label treatment including counseling and one of the following: nicotine patch, varenicline, or combination nicotine replacement therapy (nicotine patch and nicotine lozenge) are equally effective in assisting motivated smokers to quit smoking over a period of one year (Design: Randomized clinical trial).
> Among adults motivated to quit smoking, abrupt smoking cessation is the more effective method that leads to lasting abstinence over a period of 4 weeks to 6 months compared to gradual cessation, even for smokers who initially prefer to quit by gradual reduction (Design: Randomized controlled non-inferiority trial).

Topical Drug Delivery

Evidence Statements Regarding Topical Drug Delivery: Capsaicin

Strong Evidence

A single application of 8% capsaicin is more effective than a control preparation of 0.04% capsaicin for up to 12 weeks. However, there may be a need for frequent application, and it is not known whether subsequent applications of capsaicin are likely to be as effective as the first application (Design: Meta-analysis of randomized clinical trials).

Good Evidence

Low dose capsaicin (0.075%) applied 4 times per day will decrease pain up to 50% (Design: Meta-analysis of randomized trials).

Some Evidence

In patients who are being treated with capsaicin 8% patches, two methods of pre-treatment are equally effective in controlling application pain and in enabling patients to tolerate the patch: topical 4% lidocaine cream applied to the area for one hour before placement of the capsaicin patch and 50 mg oral tramadol taken 30 minutes before patch placement (Design: Randomized clinical trial).

Evidence Statements Regarding Topical Drug Delivery: Clonidine

Good Evidence

Topical clonidine gel 0.1% is likely to alleviate pain from diabetic peripheral neuropathy in patients who display a nociceptive response to the application of 0.1% capsaicin applied to the pretibial area. It is likely that patients who do not display a pain response to pretibial capsaicin are not likely to have a clinically meaningful analgesic response to clonidine gel. It is unknown if this screening test applies to other types of neuropathic pain (Design: Randomized clinical trial).

Evidence Statements Regarding Topical Drug Delivery: Ketamine and Tricyclics

Good Evidence

Neither 2% topical amitriptyline nor 1% topical ketamine reduces neuropathic pain syndromes (Design: Randomized clinical trial).

Evidence Statements Regarding Topical Drug Delivery: Lidocaine

Good Evidence

Lidocaine 5% plasters, applied for up to 12 hours to the lower extremities of patients with post-herpetic neuralgia and diabetic painful neuropathy, is non-inferior to pregabalin for the same indications. The topical lidocaine is associated with significantly fewer drug-related adverse events over 4 weeks of observation (Design: Non-inferiority randomized trial).

Some Evidence

A 5% lidocaine patch may be used as a secondary option for patients with focal neuropathic pain (Design: Randomized crossover trial).
The 8% sprays are effective for short-term, 2 week use (Design: Randomized crossover trial and open label study).

Evidence Statements Regarding Topical Drug Delivery: Topical Salicylates and Nonsalicylates

Good Evidence

Diclofenac gel (Voltaren, Solaraze) reduces pain and improves function in mild-to-moderate hand osteoarthritis (Design: Randomized clinical trial).
Topical diclofenac and ketoprofen are more effective than placebo preparations for purposes of relieving pain attributable to knee osteoarthritis (Design: Meta-analysis of randomized clinical trials).
Topical NSAIDs probably reduce the risk of GI adverse effects by approximately one third compared to oral NSAIDs (Design: Meta-analysis of randomized clinical trials).

Other Agents

A large beneficial effect of vitamin D across different chronic painful conditions is unlikely. Therefore, it is *not recommended*.

Evidence Statements Regarding Other Agents: Glucosamine

Good Evidence

Glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is *not recommended* for chronic lower spinal or non-joint pain (Design: Randomized clinical trial).

Evidence Statements Regarding Other Agents: Alpha-Lipoic Acid

Some Evidence

Alpha-lipoic acid at a dose of 600 mg per day may reduce the symptoms of painful diabetic neuropathy in the short term of 3 to 5 weeks. The effect of the intravenous route appears to be greater than that of the oral route, but the oral route may have a clinically relevant effect (Design: Meta-analysis of randomized clinical trials).

Non-Invasive Brain Stimulation

The available evidence suggests that low-frequency repetitive transcranial magnetic stimulation (rTMS), rTMS applied to the pre-frontal cortex, cranial electrotherapy stimulation (CES), and transcranial direct current stimulation (tDCS) are not effective in the treatment of chronic pain. Therefore, these devices are *not recommended* due to lack of evidence and safety concerns.

Opioid Addiction Treatment

Abrupt discontinuation of opioids is *not recommended* due to high rate of relapse due to craving and withdrawal symptoms.

Rapid detox under anesthesia is *not recommended* due to relatively high incidence of complications and high expense.

Evidence Statements Regarding Opioid Addiction Treatment

Strong Evidence

In patients being treated with opioid agonists for heroin addiction, methadone is more successful than

buprenorphine at retaining patients in treatment. The rates of opiate use, as evidenced by positive urines, are equivalent between methadone and buprenorphine (Design: Meta-analysis of randomized clinical trials).

Opioid/Chemical Treatment Program Requirements

Both ultra-rapid and rapid-detoxification are *not recommende* due to possible respiratory depression and death and the lack of evidence for long range treatment success.

See the original guideline document for time to produce effect, frequency, and optimum and maximum duration.

Orthotics/Prosthetics/Equipment

Use of cervical collars is *not recommended* for chronic cervical myofascial pain.

Personality/Psychological/Psychosocial Intervention

Evidence Statements Regarding Psychosocial Intervention

Good Evidence

Cognitive behavioral therapy (CBT), but not behavioral therapy such as biofeedback, shows weak to small effects in reducing pain and small effects on improving disability, mood, and catastrophizing in the treatment of patients with chronic pain (Design: Meta-analysis of randomized clinical trials).
CBT may reduce pain and disability in patients with chronic pain, but the magnitude of the benefit is uncertain (Design: Meta-analysis of randomized clinical trials).
There are no clinically significant differences for pain and disability between physical versus behavioral/psychologically informed and combined interventions for nonspecific chronic spinal pain (Design: Systematic review and meta-analyses of randomized clinical trials).
Psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain (Design: Meta-analysis of controlled clinical trials).
Self-regulatory interventions, such as biofeedback and relaxation training, may be equally effective (Design: Meta-analysis of controlled clinical trials).
Six group therapy sessions lasting 90 minutes each focused on CBT skills improved function and alleviated pain in uncomplicated sub-acute and chronic low back pain patients (Design: Group randomized clinical trial).
In the setting of chronic low back pain, 8 weeks of 2 hour weekly group sessions of either mindfulness based stress reduction meditation program with yoga or CBT results in small, significant improvements in physical function and reduction in pain compared to usual care at 26 weeks with no significant differences in outcomes between the 2 treatments (Design: Single-blind randomized clinical trial).
A stepped care program including CBT is more effective than usual care in veterans with chronic musculoskeletal pain. The stepped care program consists of (1) 12 weeks during which nurse case managers take a medication use history and adjust medication dosage and scheduling through telephone contacts with patients every other week, followed by (2) a 12 week step in which CBT is administered by 45 minute individual sessions by telephone every other week. Disability and pain interference with daily activity with stepped care were both superior to usual care in which patients were given printed handouts and were followed for all care by their primary treating physicians (Design: Randomized clinical trial).
In the short-term, operant therapy focused on increasing function shows small effects in reducing pain compared to waiting list controls. Most studies demonstrated a positive effect. However, it was usually below the minimal clinical significant standard. There is good evidence that no specific type of behavioral therapy is more effective than another in the treatment of patients with chronic pain (Design: Meta-analyses of randomized clinical trials).

Some Evidence

A 6-week program of cognitive-behavioral group intervention with or without physical therapy can reduce sick leave, health care utilization, and the risk for developing long-term sick leave disability (≥15 days) in workers with nonspecific low back or neck pain compared with simple verbal instruction by a physician (Design: Randomized clinical trial).
Intensive exercise coupled with CBT is as effective as posterolateral fusion for chronic un-operated low back pain (Design: Randomized clinical trial).
In the setting of chronic pain, both an 8-week mindfulness based stress reduction meditation program with yoga and an 8-week multidisciplinary pain intervention program with exercise resulted in small, significant reductions in pain intensity and pain-related distress post-intervention. However, there were no significant differences in outcomes between the 2 programs (Design: Single-blind randomized clinical trial).
CBT provided in 7 2-hour small group sessions can reduce the severity of insomnia in chronic pain patients (Design: Randomized clinical trial).
In the setting of chronic low back pain for older adults (mean age 74.5 years), an 8-week mind-body program that taught mindfulness meditation methods resulted in significant, but clinically small improvements in (1) physical function in the short-term (8 weeks) and (2) current and most severe pain in the past week in the long term (6 months) compared to a healthy aging education program (Design: Single-blind randomized clinical trial).

Additional Studies Not Resulting in Evidence Statements

A study using functional magnetic imaging compared mindful practitioners with controls and found that mindfulness did not decrease pain but did decrease pain unpleasantness by 22% and anxiety by 23%. Further studies would be needed to establish this as a recommendation.
Another recent Cochrane review found only low quality studies of cognitive behavioral therapy for chronic neck pain which suggested some benefit but with low clinical significance.

Summary of Evidence Regarding Psychosocial Intervention

Based on the multiple studies with good evidence listed above, there is strong evidence supporting CBT, particularly in conjunction with other active therapy, to decrease pain and disability for chronic pain patients. However, the magnitude of the change is not likely to be large.

See the original guideline document for time to produce effect, frequency, and optimum and maximum duration for cognitive behavioral therapy or similar treatment and other psychological/psychiatric interventions.

Restriction of Activities

Continuation of normal daily activities is the recommendation for most patients since immobility will negatively affect rehabilitation.

Return-To-Work

The following should be considered when attempting to return an injured worker with chronic pain to work:

Job history interview
Coordination of care
Communication
Establishment of return-to-work status
Establishment of activity level restrictions
Rehabilitation and return-to-work
Vocational assistance

Therapy—Active

Evidence Statements Regarding Patient Education

Good Evidence

Pain neuroscience education combined with a physical intervention is more effective in reducing pain, improving disability, and reducing healthcare utilization compared with either usual care, exercise, other education or another control group for the treatment of patients with chronic musculoskeletal pain (Design: Narrative systematic review of randomized clinical trials).

Some Evidence

A cognitive intervention consisting of 2 consultations lasting 1 hour each with a physical medicine specialist and a physical therapist covering coping strategies and patient education on motion produces short-term reductions in sub-acute back disability (Design: Randomized clinical trial).
In the setting of non-specific chronic low back pain, patient-centered cognitive functional therapy from physical therapists produced superior outcomes for pain reduction and functional improvement compared with traditional manual therapy and exercise at post-intervention and at 12-month follow-up (Design: Single-blind randomized clinical trial).

The following active therapies are listed in alphabetical order. See the original guideline document for specific information about individual therapies, including indications, time to produce effect, frequency, and optimum and maximum duration.

Activities of daily living (ADL)
Aquatic therapy
Functional activities
Functional electrical stimulation
Neuromuscular re-education
Spinal stabilization
Therapeutic exercise
Work conditioning
Work simulation

Evidence Statements Regarding Aquatic Therapy

Good Evidence

Aquatic exercise and land-based exercise show comparable outcomes for function and mobility among people with symptomatic osteoarthritis of the knee or hip (Design: Systematic review and meta-analysis of randomized clinical trials).

Evidence Statements Regarding Neuromuscular Re-education

Some Evidence

There is a modest benefit from adding a back school to other treatments such as NSAIDs, massage, transcutaneous electrical nerve stimulation (TENS), and other physical therapy modalities (Design: Systematic review of randomized clinical trials).

Evidence Statements Regarding Therapeutic Exercise

Strong Evidence

In the short, intermediate, and long term, motor control exercises that emphasize the transversus abdominis and multifidi are at least as effective as other forms of exercise and manual therapy. They are possibly more effective than other minimal interventions in reducing pain and improving disability in patients for the treatment of chronic non-specific low back pain (Design: Meta-analyses of randomized clinical trials).
Land-based exercise shows a small clinically important benefit for the relief of pain and improvement in function at the completion of a supervised exercise program and these benefits are sustained for at least another 3 to 6 months among people with symptomatic osteoarthritis of the hip (Design:

Meta-analysis of randomized clinical trials).

Good Evidence

A 12-week course of treatment in the McKenzie method is at most modestly more effective than spinal manipulation of similar duration in reducing disability in patients with persistent (more than 6 weeks duration, mean = 95 weeks) nonspecific low back pain, although a clinically relevant difference was not apparent. The McKenzie method should not be utilized if there is severe nerve root involvement with motor, sensory, or reflex abnormality (Design: Randomized clinical trial).
Pilates is more effective in reducing pain and improving disability compared with a minimal intervention at intermediate term follow-up, but Pilates is equally as effective as other forms of exercise in improving disability at short- or intermediate-term follow-up for the treatment of patients with chronic non-specific low back pain (Design: Meta-analysis of randomized clinical trials).
Exercise alone or as part of a multidisciplinary program results in decreased disability for workers with non-acute low back pain (Design: Meta-analysis of randomized clinical trials).
Supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee (Design: Systematic review and meta-analysis of randomized clinical trials).
Land-based exercise shows a moderate clinically important benefit for the relief of pain and improvement in function at the completion of a supervised exercise program and shows that somewhat smaller benefits are sustained for at least another 2 to 6 months among people with symptomatic osteoarthritis of the knee (Design: Meta-analysis of randomized clinical trials).

Some Evidence

An unsupervised 12-week, periodized musculoskeletal rehabilitation (PMR) program of weight training conducted 2, 3, or 4 days a week is effective at improving musculoskeletal strength and quality of life and at reducing pain and disability in untrained persons with chronic low back pain. The 4 days a week training volume is most effective. The volume (total number of reps) of PMR exercise prescribed is important (Design: Randomized clinical trial).
Trunk balance exercises combined with flexibility exercises are more effective than a combination of strength and flexibility exercises in reducing disability and improving physical function in patients with chronic low back pain (Design: Single-blind randomized clinical trial).
An exercise program which includes resistance training of the cervical and scapulothoracic muscles, combined with stretching of the same muscles, is likely to be beneficial for mechanical neck pain. Cervicoscapular endurance exercises are beneficial for chronic cervicogenic headache. General fitness exercises and upper extremity exercises are unlikely by themselves to be beneficial for mechanical neck pain and are therefore *not recommended* (Design: Meta-analysis of randomized clinical trials).
There is no significant difference in the effectiveness of an 12-week, 20 session comprehensive supervised exercise program and an unsupervised simple exercise program with advice for improvement in average pain intensity in the preceding week in people with a mild chronic whiplash-associated disorder even though both interventions resulted in small reductions of pain over 12 months (Design: Assessor single-blind randomized clinical trial).
A 4-month intervention for chronic neck pain patients containing pain education, specific exercises and graded activity training shows a significant effect, although clinically small, on improved physical and mental health related quality of life compared with controls receiving pain education alone. Good adherence increased the effect in favor of the exercise group (Design: Assessor single-blind randomized controlled superiority multicenter clinical trial).
12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (1 year) in those who have chronic low back pain (Design: Assessor single-blinded randomized controlled trial).
Intensive exercise coupled with cognitive behavioral therapy is as effective for chronic un-operated low back pain as posterolateral fusion (Design: Randomized clinical trial).
In the setting of non-specific chronic low back pain, patient-centered cognitive functional therapy from physical therapists produced superior outcomes for pain reduction and functional improvement compared with traditional manual therapy and exercise at post-intervention and at 12-month follow-

up (Design: Single-blind randomized clinical trial).
There is no significant difference in the effectiveness of an 8-week supervised walking program, an evidence-based group exercise class, and usual physiotherapy for improvement in functional disability after 6 months for people with chronic low back pain even though all 3 interventions resulted in small, significant improvements in physical function, reduction of pain, quality of life, and fear avoidance over time (Design: Assessor single-blind randomized clinical trial).
12 weeks of behavioral graded activity does not result in better long-term effectiveness in reducing pain or improving function at 5 years than usual exercise therapy in patients with osteoarthritis (OA) of the hip or knee (Design: Randomized clinical trial).

Evidence Statements Regarding Yoga

Strong Evidence

Yoga has small to moderate advantages over providing only a booklet in reducing low back pain and back-specific disability, but there is no evidence that yoga is superior to stretching and strengthening classes led by a licensed physical therapist (Design: Meta-analysis of randomized clinical trials).

Good Evidence

In the setting of chronic low back pain, 8 weeks of 2 hour weekly group sessions of either mindfulness based stress reduction meditation program with yoga or CBT results in small, significant improvements in physical function and reduction in pain compared to usual care at 26 weeks with no significant differences in outcomes between the 2 treatments (Design: Single-blind randomized clinical trial).

Some Evidence

Iyengar yoga, which avoids back bending, results in improved function and decreased chronic mechanical low back pain for up to 6 months. Instruction occurred 2 times per week for 24 weeks and was coupled with home exercise. One quarter of the participants dropped out (Design: Randomized clinical trial).
In the setting of chronic pain, both an 8-week mindfulness based stress reduction meditation program with yoga and an 8-week multidisciplinary pain intervention program with exercise resulted in small, significant reductions in pain intensity and pain-related distress post intervention but with no significant differences in outcomes between the 2 programs (Design: Single-blind randomized clinical trial).

Therapy—Passive

The following passive therapies are listed in alphabetical order. See the original guideline document for indications, complications, contraindications, time to produce effect, frequency, and optimum and maximum duration.

Electrical stimulation (Unattended)
Iontophoresis
Low level laser
Manual treatment including manipulation
Manipulation under general Anesthesia (MUA)
Manipulation under joint anesthesia (MUJA)
Massage—manual or mechanical
Mobilization (soft tissue)
Percutaneous electrical nerve stimulation (PENS)
Superficial heat and cold therapy (including infrared therapy)
Traction—manual
Traction—mechanical
Transcutaneous electrical nerve stimulation
Trigger point dry needling (TDN)
Ultrasound (including phonophoresis)

Vertebral axial decompression (VAX-D)/DRX, 900

Low Level Laser

Low level laser is *not recommended* as there is no proven benefit for this intervention due to lack of studies of sufficient quality. There is not enough research at this time to support this modality in the treatment of chronic pain. Results of low level laser have been mixed and often poor quality.

Manual Treatment Including Manipulation

Evidence Statements Regarding Manual Treatment for Neck

Good Evidence

Multiple sessions of thoracic manipulation was more effective in reducing short- and intermediate-term chronic neck pain and improving function and quality of life when compared with multiple sessions of an inactive control for the treatment of patients with chronic neck pain (Design: Meta-analyses of randomized clinical trials and quasi RCTs).

Some Evidence

A 3-week program of twice weekly home neck exercises with manual physical therapy that includes joint mobilization, muscle energy, and stretching, reduces neck pain and disability compared with a minimal intervention for patients with chronic neck pain at 6 weeks follow-up. It did not persist at one year follow-up (Design: Randomized clinical trial).
Combination of exercise and spinal manipulation is more effective than manipulation alone in relieving chronic neck pain and that these advantages remain for more than 1 year after the end of treatment (Design: Randomized clinical trials).
Craniosacral therapy for chronic nonspecific neck pain, performed by a physical therapist trained in the technique, is superior to sham treatment in reducing neck pain intensity at 8 weeks and probably at 20 weeks (Design: Randomized clinical trial).
12 weeks of supervised high-dose exercise, 20 sessions 1-2 times per week, with or without spinal manipulative therapy, resulted in significantly greater pain reduction in the short-term (12 weeks) compared to low-dose home exercise with advice, in people with chronic neck pain. Disability reduction was also significantly greater. However, the low dose group had only 2 visits with a provider which would generally be expected to diminish the outcome measurements. The effect decreased at one year follow-up (Design: Assessor single-blinded randomized controlled trial).

Evidence Statements Regarding Manual Treatment for Low Back

Good Evidence

Spinal manipulative therapy (SMT) is comparable to exercise, standard medical care, and physiotherapy in reducing chronic low back pain, and SMT does not provide a clinically important superior pain relief over these interventions (Design: Meta-analysis of randomized clinical trials).
Two sessions of thrust manipulation of the thoracolumbar spine followed by an exercise regimen leads to better low back function at 6 months than oscillatory non-thrust manipulation in patients with subacute low back pain. The study found patients with the following characteristics were likely to benefit from the program: segmental hypomobility, no symptoms distal to the knee, low fear-avoidance scores, and preservation of at least 35 degrees of internal rotation in at least one hip (Design: Randomized controlled trial).

Some Evidence

Spinal manipulation/mobilization, followed by active exercises, may be effective for the reduction of disability from nonspecific low back pain lasting more than 12 weeks (Design: Randomized clinical trial).
12 sessions of spinal manipulation in 6 weeks from a chiropractor yields the most favorable pain reduction and functional disability improvement compared to a hands-on control in the short-term

(12 weeks) for chronic nonspecific low back pain. There was little difference in pain and disability scores and no clinically important differences between spinal manipulation dose groups of 6, 12, or 18 manipulations, making it difficult to recommend one treatment dose over another (Design: Assessor single-blinded randomized controlled trial).
12 weeks of supervised high-dose exercise, spinal manipulative therapy, or low-dose home exercise with advice are all equally effective for reducing pain in the short- and long-term (1 year) in those who have chronic low back pain (Design: Assessor single-blinded randomized controlled trial).
A combination of spinal manipulation and exercise is more effective than exercise alone in reducing pain and improving function of low back pain for 1 year (Design: Randomized clinical trial).

Evidence Statements Regarding Manual Treatment for Knee

Good Evidence

Supervised exercise therapy with added manual mobilization shows moderate, clinically important reductions in pain compared to non-exercise controls in people with osteoarthritis of the knee (Design: Systematic review and meta-analysis of randomized clinical trials).

Manipulation Under General Anesthesia (MUA)

There have been no high quality studies to justify MUA's benefits given the risks of general anesthetic and conscious sedation. It is *not recommended*.

Manipulation Under Joint Anesthesia (MUJA)

There are no controlled clinical trials to support the use of MUJA. It is *not recommended*.

Masssage—Manual or Mechanical

Evidence Statements Regarding Massage

Good Evidence

Massage therapy in combination with exercise reduces pain and improves function short-term for patients with subacute low back pain (Design: Randomized clinical trial, systematic review of controlled clinical trials, randomized clinical trial).

Some Evidence

10 weeks of either relaxation massage or structural massage are more effective than usual care and equally effective in improving functional disability and reducing symptoms of pain in people with chronic low back pain with benefits lasting at least 6 months (Design: Single-blind parallel group randomized controlled trial).
In the setting of chronic neck pain, 4 weeks of weekly hour-long massage leads to benefits with both pain and function, and there are incremental benefits from multiple massage sessions per week (up to 3 sessions) over a single massage session (Design: Randomized clinical trial with six intervention arms).

Percutaneous Electrical Nerve Stimulation (PENS)

There is good evidence that PENS produces improvement of pain and function compared to placebo; however, there is no evidence that the effect is prolonged after the initial 3 week treatment episode. There are no well done studies that show PENS performs better than TENS for chronic pain patients. PENS is more invasive, requires a trained health care provider and has no clear long-term effect; therefore it is *not generally recommended*.

Traction—Mechanical

There is some evidence that mechanical traction, using specific, instrumented axial distraction technique, is not more effective than active graded therapy without mechanical traction. Therefore, mechanical traction is *not recommended* for chronic axial spine pain.

Vertebral Axial Decompression (VAX-D)/DRX, 9000

These are motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000. There are no good studies to support their use. They are *not recommended*.

Therapeutic Procedures—Operative

The following operative procedures are considered:

Neurostimulation
Dorsal root ganglion stimulator
Peripheral nerve stimulation
Intrathecal drug delivery
Neuroablation with rhizotomy as the exception
Dorsal nerve root resection

See the original guideline document for complications, surgical indications, contraindications, operative treatment, post-operative considerations, and post-operative therapy.

Neurostimulation

Currently, traditional spinal cord stimulators are *not recommended* for axial spine pain. Traditional spinal cord stimulation (SCS) is *not recommended* for patients with the major limiting factor of persistent axial spine pain.

Evidence Statement Regarding Neurostimulation

Some Evidence

SCS is superior to reoperation in the setting of persistent radicular pain after lumbosacral spine surgery. Success was defined as achieving 50% or more pain relief (Design: Randomized clinical trial).
SCS is superior to conventional medical management in the setting of persistent radicular pain after lumbosacral spine surgery. Success was defined as achieving 50% or more pain relief. However, the study could not demonstrate increased return to work (Design: Randomized clinical trial).
A high-frequency, 10 KHz spinal cord stimulator is more effective than a traditional low frequency 50 Hz stimulator in reducing both back pain and leg pain in patients who have had a successful trial of an external stimulator. Two-thirds of the patients had radiculopathy and one-half had predominant back pain. The high frequency device appears to lead to greater patient satisfaction than the low frequency device, which is likely to be related to the fact that the high frequency device does not produce paresthesias in order to produce a pain response. In contrast to the low frequency stimulator, which requires recharging about twice per month, the high frequency stimulator is recommended for daily recharging for 30 to 45 minutes (Design: Randomized controlled trial. The study was designed as a non-inferiority study for the experimental SCS system, and testing for superiority was done if the non-inferiority margins were met for the outcomes under consideration).
SCS is superior to re-operation and conventional medical management for severely disabled patients who have failed conventional treatment and have CRPS I or failed back surgery with persistent radicular neuropathic pain (Design: Randomized clinical trials).

Intrathecal Drug Delivery

Intrathecal drug delivery is *not generally recommended*.

Due to lack of proven efficacy and safety, the following medications are *not recommended*: magnesium, benzodiazepines, neostigmine, tramadol, and ketamine.

Neuroablation with Rhizotomy as the Exception

The use of neuroablative procedures is *not recommended*, except medial branch nerve rhizotomy, for injured workers with chronic pain.

Doral Nerve Root Resection

This procedure is *not recommended*.

Maintenance Management

Maintenance care in chronic pain disorder (CPD) requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost-effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can design medically appropriate programs. Designating a primary physician for maintenance management is strongly recommended.

It is recommended that valid functional tests are used with treatments to track efficacy. The following are specific maintenance interventions and parameters (see the original guideline document for frequency and maintenance duration).

- Home exercise programs and exercise equipment
- Exercise programs requiring special facilities
- Patient education management
- Psychological management
- Non-opioid medication management
- Opioid medication management
- Therapy management
- Injection therapy
- Purchase or rental of durable medical equipment (DME)

Definitions

Grades of Recommendation

Some means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.

Good means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.

Strong means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Chronic pain disorder, including:

Nociceptive pain
Neuropathic pain
Psychogenic pain

Guideline Category

Counseling

Management

Rehabilitation

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurological Surgery

Neurology

Physical Medicine and Rehabilitation

Psychiatry

Psychology

Rheumatology

Surgery

Intended Users

Advanced Practice Nurses

Chiropractors

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Occupational Therapists

Patients

Physical Therapists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Substance Use Disorders Treatment Providers

Utilization Management

Guideline Objective(s)

To provide advisory and educational guidelines for the treatment of chronic pain disorder that are enforceable under the Colorado Workers' Compensation Rules of Procedure

Target Population

Individuals qualifying under Colorado's Workers' Compensation Act as injured workers with chronic pain

Interventions and Practices Considered

Non-operative Therapeutic Procedures*

- Acupuncture
- Biofeedback
- Complementary medicine
- Direct cortical stimulation (not recommended)
- Treatment of sleep disturbances
- Education/informed/shared decision making
- Therapeutic injections
  - Epidural steroid injections (ESI)
  - Intradiscal steroid injection (not recommended)
  - Sacroiliac joint injection
  - Transforaminal injection with etanercept (not recommended)
  - Zygapophyseal (facet) injection
  - Botulinum toxin injections
  - Epiduroscopy and epidural lysis of adhesions (not recommended)
  - Prolotherapy (not recommended)
  - Radio frequency ablation - dorsal nerve root ganglion (not recommended)
  - Radio frequency ablation - genicular nerves
  - Radio frequency denervation - medial branch neurotomy/facet rhizotomy
  - Radio frequency denervation - sacro-iliac joint cooled
  - Transdiscal biacuplasty (not recommended)
  - Trigger point injections
- Interdisciplinary rehabilitation programs (formal and informal)
- Non-invasive brain stimulation (not recommended)
- Opioid addiction treatment
- Opioid/chemical treatment programs
- Medications and medical management
  - Alpha-acting agents
  - Anticonvulsants
  - Antidepressants
  - Cannabinoid products (not recommended as per federal law)
  - Hypnotics and sedatives
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Opioids

- Post-operative pain management
- Skeletal muscle relaxants
- Smoking cessation medications and treatment
- Topical drug delivery
- Other agents (glucosamine)

- Orthotics/prosthetics equipment
- Patient education
- Personality/psychological/psychosocial/psychiatric interventions
- Restriction of activities
- Return to work
  - Job history interview
  - Coordination of care
  - Communication
  - Establishment of a return-to-work status
  - Establishment of activity level restrictions
  - Rehabilitation and return to work
  - Vocational assistance
- Active therapy
  - Activities of daily living (ADL)
  - Aquatic therapy
  - Functional activities
  - Functional electrical stimulation
  - Neuromuscular re-education
  - Spinal stabilization
  - Therapeutic exercise
  - Work conditioning
  - Work simulation
- Passive therapy
  - Electrical stimulation (unattended)
  - Iontophoresis
  - Low level laser (not recommended)
  - Manual treatment including manipulation
  - Manipulation under general anesthesia (MUA) (not recommended)
  - Manipulation under joint anesthesia (MUJA) (not recommended)
  - Manual or mechanical massage
  - Joint or soft tissue mobilization
  - Percutaneous electrical nerve stimulation (PENS)
  - Superficial heat and cold therapy (including infrared therapy)
  - Manual or mechanical traction
  - Transcutaneous electrical nerve stimulation (TENS)
  - Trigger point dry needling (TDN)
  - Ultrasound (including phonophoresis)
  - Vertebral axial decompression (VAX-D)/DRX, 9000 (not recommended)

Operative Therapeutic Procedures*

- Neurostimulation
- Dorsal root ganglion stimulator
- Peripheral nerve stimulation
- Intrathecal drug delivery
- Neuroablation with rhizotomy as the exception
- Dorsal nerve root resection (not recommended)

Maintenance Management

Home exercise programs and exercise equipment
Exercise programs requiring special facilities
Patient education management
Psychological management
Non-opioid medication management
Opioid medication management
Therapy management
Injection therapy
Purchase or rental of durable medical equipment

*Note: See the "Major Recommendations" field and the original guideline document. Not all of the listed interventions and practices are recommended routinely or generally.

Major Outcomes Considered

- Functional improvement (time to return to work, ability to return to original job, etc.)
- Change in pain scores (visual analogue scale, Oswestry Disability Questionnaire score, etc.)
- Duration of therapeutic effect
- Time to recovery
- Relapse rate
- Side effects or complications

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Literature Search Strategy

Studies were identified through the electronic database of PubMed (with specified search topics), and from articles identified by searches. For some articles, the literature citation database Web of Science was used when it was desirable to find literature that cited a particular article. Relevant evidence statements from Cochrane and British Medical Journal (BMJ) Clinical Evidence were reviewed. Selected guidelines/systematic reviews were also reviewed. The reference lists from other literature and tables of contents from related journals were scanned for relevant articles (i.e., a hand search of literature was completed). Suggestions from various volunteer advisory bodies to the Division of Workers' Compensation were solicited.

Literature reviewed was in English. Literature searches were limited according to study type and human adults. Only randomized controlled trials (RCTs) or meta-analyses were used for evidence statements regarding treatment. RCTs that compared an intervention with not using that intervention (e.g., surgery and non-operative treatment) were designated as more relevant to workers' compensation guidelines than those RCTs which compared variations on technique or types of devices.

Beginning with the Traumatic Brain Injury Medical Treatment Guideline Revision of 2012, RCTs may not have been critiqued individually if they were included in a critiqued meta-analysis of high quality. Relevant RCTs published after a Cochrane meta-analysis were evaluated as to whether they would have

likely met the Cochrane inclusion criteria. If so, the Cochrane software (RevMan) was used to update the pooled effect measure and compare it with the original Cochrane report. Diagnostic accuracy studies were critiqued for diagnostic testing evidence. Cohort, cross-sectional and case-control studies were critiqued for causation evidence statements. Literature which did not meet requirements for evidence statements could be referenced if it furnished useful background information or described interventions which are considered generally accepted by a consensus of health care providers. This information sometimes contributed to consensus decisions by the multidisciplinary task force drafting the guidelines. Literature that was determined to be unrelated to the clinical issue, did not reflect interventions likely to occur in Colorado, or which had such poor quality on initial review that it could not qualify for evidence nor provide meaningful input was not critiqued. All articles sent by the public were formally reviewed.

Specific Search Strategy

All searches were done on PubMed and the Cochrane Library. The literature search included articles published through December 2016. See the Search Strategy and Study Selection document (see the "Availability of Companion Documents" field) for beginning dates of searches and the search terms.

Study Selection

Inclusion criteria: Studies in English; human; adults; RCT, systematic review, or meta-analysis

Exclusion criteria: Article titles containing an obvious mismatch with search criteria and search terms were eliminated (e.g., pediatric population, wrong condition). Abstracts were reviewed to exclude articles based on the following criteria:

- Lack of relevancy to workers' compensation population
- Major obvious errors in study protocol (e.g., lack of control group even though study was listed as an RCT)
- Study was included in a meta-analysis reviewed by Division staff (e.g., Cochrane Collaboration, BMJ Clinical Evidence
- Study was published outside of time frame
- Cadaverous studies
- Preliminary results
- Healthy volunteers
- Studies not applicable to conditions covered by the Division's treatment guidelines (e.g., tumor studies were excluded)
- Studies too technical in nature to meet the objective of the guideline (e.g., study comparing types of screws used in surgery)

Other literature was included in addition to sources identified by searches in the electronic databases. Some references were carried over from earlier versions of the guideline. Other articles were selected by hand searches of published literature. Articles submitted by the public and from volunteer advisory bodies to the Colorado Division of Workers' Compensation were also reviewed. All reviewed articles were included in the full Bibliography (see the "Availability of Companion Documents" field), but not all references qualified to be cited in the guideline. In total, 1577 references were included in the full bibliography.

Included studies were reviewed for quality and relevancy. Some articles were excluded based on a "second tier" of exclusion criteria:

- Sample size too small <20 per group
- Animal study
- No outcomes of interest
- Population too old/young (<18 or >70)
- Study protocol and not an RCT
- Pilot study
- Surgical technique
- Included in a meta-analysis, systematic review, or Cochrane

Review includes only one relevant RCT (RCT critiqued instead)
No RCTs included (for a systematic review)
Lack of assessor blinding (mainly drug studies)
Inclusion criteria: ≥3 months of pain
Not actually an RCT (lack of randomization)
Narrative review
Editorial
Uninformative
Not relevant or of interest
Follow-up too short (<12 weeks)
Study is too old (2010 or older)
Article unobtainable or not in English
Superseded by a more recent review
No primary outcome
Critiqued in previous version of the guideline

Number of Source Documents

Number of articles identified by database search: 1447

Number of articles included for review after exclusion criteria were applied to database search results: 1007

Number of articles used to support evidence statements: 161

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See the Colorado Division of Workers' Compensation Web site , "Chronic Pain Disorder," for rating schemes for various types of studies.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Studies remaining after application of the exclusion criteria qualified for critique using the Division's Literature Critique Criteria. Studies assessed as "adequate" or "high quality" were used for evidence statements. Three levels ("some," "good," and "strong") were then used to describe strength of evidence for recommendations based on the amount and quality of the supporting literature. For more information regarding literature assessment and resulting evidence statements, see Chronic Pain Disorder on the Division's Web site for (a) Literature Critique Criteria, which are under "Assessment Criteria for Critiques" on the Web site, (b) the Evidence Summary/Table, and (c) Critiques for individual articles (see the "Availability of Companion documents" field).

Some articles were excluded after a critique was started, and reasons for exclusion were provided in the critique. A shortened version of the critique was completed if reasons for exclusion were identified early in the critique process.

Articles that were given a complete critique were given an assessment of "inadequate," "adequate," or "high quality." It should be noted that one article may be graded at different levels for different interventions. Also, in multiple cases, literature from the Cochrane Collaboration was reviewed. When Division of Workers' Compensation staff completed additional statistical pooling using RevMan (Cochrane Collaboration of Systematic Reviews), this is noted in the "Assessment by DOWC Staff" column of the critique.

For those studies deemed inadequate, a brief rationale was provided. The articles that were graded as either adequate or high quality were used for evidence statements. Three levels ("some evidence," "good evidence," and "strong evidence") were then used to describe strength of evidence for recommendations based on the amount and quality of the supporting literature. These levels of evidence are defined in the General Guidelines Principles, which are located in each of the Division Medical Treatment Guidelines.

Because the Division synthesizes the medical evidence as much as possible, one assessment (or group of assessments) may potentially create more than one evidence statement. It is also possible that multiple assessments may be combined for a higher level of evidence (e.g., two "adequate" studies might strengthen the evidence supporting a recommendation from "some" to "good").

Note that other recommendations in the Medical Treatment Guideline are consensus statements. Consensus statements are used only when adequate evidence was not available in the published literature reviewed by the Division or when published evidence was conflicting. The multidisciplinary Task Force makes consensus recommendations based on general medical principles and apply the following values: functional benefit to the patient, acceptable risk and morbidity, length of disability and timeframe to recovery, and lastly, acceptable cost. Consensus statements are often designated in Medical Treatment Guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

Methods Used to Formulate the Recommendations

Expert Consensus

Other

Description of Methods Used to Formulate the Recommendations

Studies assessed as "adequate" or "high quality" were used for evidence statements. Three levels ("some," "good," and "strong") were then used to describe strength of evidence for recommendations based on the amount and quality of the supporting literature.

Expert Consensus statements were used when adequate evidence was not available in published literature or when published evidence was conflicting. Literature not meeting requirements for evidence statements was referenced if it described interventions which are generally accepted by a consensus of health care providers. This information, when available, contributed to consensus decisions for recommendations by the multi-disciplinary task force drafting the guidelines.

These recommendations were determined by the judgment of experienced professionals based on general medical principles. When making these recommendations, the task force considered the following values: functional benefit to patient, acceptable risk and morbidity, and length of disability and timeframe to recovery. Acceptable cost is considered, all else being equal. Consensus recommendation are typically designated with the language "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established."

Medical Treatment Guidelines - Updating Process

The Division's Medical Treatment Guidelines updating process is completed in several stages. Initially, current medical literature related to the guideline is reviewed, critiqued, and graded by the Division. Next, appropriate medical evidence and consensus are incorporated concurrently into the Guideline, section by section by the Division and a multidisciplinary Task Force. During this stage, Task Force members are sometimes appointed for projects, working in sub-groups or individually, according to the task. Guideline updating processes and resources dedicated by the Division to support the Task Force include:

- Medical literature review and grading, completed by a professional research methodologist and epidemiologist
- Evidence and consensus parameters to assist in the revision and evaluation of treatment recommendations
- A multidisciplinary Advisory Panel and other advisory bodies to provide clinical feedback to the Task Force and the Division
- Administrative support and coordination, allowing participants to focus on clinical issues
- Opportunities for members to provide feedback on ways to improve the update process

Selection of Task Force Members

Health care disciplines required to participate in the Task Force process are identified. Individuals selected should be Level I or II Accredited Providers (if applicable), Board Certified in their area of specialty, in good standing within their medical specialty organization, and specialize in treatment of injured workers. Task force membership also includes non-physician members of the workers' compensation system, such as: therapists, psychologists, attorneys, and risk managers. Prior task force participation is not necessary.

Medical Literature Review

Articles are selected for review based on relevance and informativeness after viewing their titles and abstracts. Published journal articles are selected to be critiqued by the research methodologist and epidemiologist prior to distribution. Unpublished articles or office handouts submitted by Task Force members or the public are reviewed and critiqued by the medical director, research methodologist and epidemiologist, who then communicate directly with the submitting individual regarding quality and relevance. The submitting individual retains the prerogative of distributing the material to the Task Force. Other unspecified material and public commentary received or solicited by the Division is reviewed and critiqued, as appropriate, and distributed at the discretion of the medical director and medical policy staff. Many articles are included in the bibliography without critiques or assessment for evidence. These articles are considered to provide pertinent information whether or not they lend themselves to formal evaluation for levels of evidence.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Some means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.

Good means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.

Strong means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect.

Cost Analysis

Published cost analyses were reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Advisory Panel

The next stage of the guideline update process includes an additional review, conducted by an Advisory Panel and other advisory bodies that may consist of past Task Force members and knowledgeable professionals representing medical specialty organizations, associations, and other stakeholder groups. Professionals who represent adjunct aspects of patient care, such as risk managers, case managers, and insurers, are also included in this stage. The purpose of this review is to provide additional sources of expertise in order to finalize draft guideline material developed by the Task Force.

Solicitation of Public Commentary

An active, open process to solicit public commentary is in place in order to maximize community-based physician and other stakeholder input and support. Contact with Accredited Providers is done through direct mailings and at Accreditation seminars.

Post Task Force Questionnaire

A survey is sent to all Task Force members once the updated draft guidelines are completed. The survey rates Task Force participants' satisfaction with the process and evaluates Division personnel and performance. Information may be used to improve future Task Force processes.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is provided for each evidence statement (see the "Major Recommendations" field).

Only graded and critiqued randomized controlled trials or meta-analyses were used for evidence statements.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Optimal medical and functional outcomes for injured workers with chronic pain disorders

Evidence of benefits of specific treatment interventions is reviewed in the relevant sections of the original guideline document and in the evidence summary companion document (see the "Availability of

Companion Documents" field).

Potential Harms

- Injuries, side effects, or infections from therapeutic injections
- Side effects and drug interactions from medications
- Complications from operative procedures
- Injury from device or component failure

Refer to specific sections of the "Major Recommendations" field and original guideline document for detailed descriptions of potential harms.

Contraindications

Contraindications

See specific sections of the original guideline document for major and relative contraindications.

Qualifying Statements

Qualifying Statements

- To properly utilize this document, the reader should not skip nor overlook any sections.
- This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Colorado's Workers' Compensation Act as injured workers with chronic pain.
- Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.
- The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the office of administrative courts.

Implementation of the Guideline

Description of Implementation Strategy

The principles summarized below are key to the intended implementation of all Division of Workers' Compensation medical treatment guidelines and critical to the reader's application of the guidelines in the original guideline document.

> Application of Guidelines. The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the office of

administrative courts.
Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain injuries and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies to educate patients, employers, insurance systems, policy makers and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimens which employ functional, restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention. Facilitation through language interpretation, when necessary, is a priority and part of the medical care treatment protocol.
Informed Decision Making. Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.
Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient adherence, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in the original guideline document.
Active Interventions. Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.
Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to: positional tolerances, range-of-motion (ROM), strength, endurance, activities of daily living, ability to function at work, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings. Patient completed functional questionnaires such as those recommended by the Division as part of Quality Performance and Outcomes Payments (QPOP, see Rule 18-8) and/or the Patient Specific Functional Scale can provide useful additional confirmation.
Re-evaluation of Treatment No Less Than Every 3 to 4 Weeks. If a given treatment or modality is not producing positive results within 3 to 4 weeks or within the time to produce effect in the guidelines, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.
Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.
6-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than 6 months. The emphasis within these

guidelines is to move patients along a continuum of care and return-to-work within a 6-month time frame, whenever possible. It is important to note that time frames may be less pertinent for injuries that do not involve work-time loss or are not occupationally related.

Return-to-Work. A return-to-work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific physical limitations, and the patient should never be released to non-specific and vague descriptions such as "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage, and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, from including, but not limited to: an occupational health nurse, occupational therapist, vocational rehabilitation specialist, an industrial hygienist, or another professional.

Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting for those patients who are failing to make expected progress 6 to 12 weeks after initiation of treatment of an injury. Therefore all chronic pain patients should have a documented psychological evaluation and psychological treatment as appropriate to address issues of chronic pains. it is also appropriate to clinically reassess the patient, function goals, and differential diagnosis. The Division recognizes that 3% to 10% of all industrially injured patients will not recover within the timelines outlined in the original guideline document, despite optimal care. Such individuals may require treatments beyond the timelines discussed within the original guideline document, but such treatment requires clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

Guideline Recommendations and Inclusion of Medical Evidence. All recommendations are based on available evidence and/or consensus judgment. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply:

> Consensus means the judgment of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."
>
> "Some evidence" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.
>
> "Good evidence" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.
>
> "Strong evidence" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect.

All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, irrespective of the level of evidence or consensus attached to them. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

Treatment of Preexisting Conditions. The conditions that preexisted the work injury/disease will need to be managed under two circumstances: (a) a preexisting condition exacerbated by a work injury/disease should be treated until the patient has returned to their objectively verified prior level of functioning or maximum medical improvement (MMI); and (b) a preexisting condition not directly

caused by a work injury/disease but which may prevent recovery from that injury should be treated until its objectively verified negative impact has been controlled. The focus of treatment should remain on the work injury/disease.

This guideline document should be interpreted within the parameters of these guideline principles that may lead to more optimal medical and functional outcomes for injured workers.

Implementation Tools

Chart Documentation/Checklists/Forms

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Chronic pain disorder medical treatment guideline. Denver (CO): Colorado Division of Workers' Compensation; 2017 Nov 30. 178 p.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Nov 30

Guideline Developer(s)

Colorado Division of Workers' Compensation - State/Local Government Agency [U.S.]

Source(s) of Funding

Colorado Division of Workers' Compensation

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

Division staff include a medical director (MD, MPH, FACOEM) and two research staff who review and critique all literature used for recommendations (a research methodologist, MD, MSPH; and an epidemiologist, MS). Several other staff members are involved, including a unit supervisor (DPT), coordinator (PhD, CCC-SLP), and editor.

The external task force used to write recommendations included the following representatives: chiropractor, claimant's attorney (x2, one as alternate), doctor of osteopathic medicine, neurologist, nurse case manager, occupational medicine physician, occupational therapist, pain management physician (x2, one as alternate), pharmacist, physical medicine and rehabilitation physician (x3, one as a spinal cord stimulator specialist), physical therapist, psychologist, psychiatrist, and risk manager.

There was also an external advisory panel used to review the proposed guideline. The members who responded included the following professionals: attorney (x3; claimant's and respondent's), chiropractor (x2), doctor of osteopathic medicine, internal medicine physician, medical directors and experts from other states (x3), neurologist (x1), nurse case manager (x4), occupational medicine physician (x2), occupational therapist (x2), pain management doctor (x2), pharmacist (x2), physical medicine and rehabilitation physician (x3, one as a spinal cord stimulator specialist), physical therapist (x4), psychologist (x2), psychiatrist and risk manager (x2).

Financial Disclosures/Conflicts of Interest

Every task force and advisory panel member completes a written disclosures and conflict of interest form.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Colorado Division of Workers' Compensation. Chronic pain disorder medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2011 Dec 27. 110 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Colorado Division of Workers' Compensation Web site .

Availability of Companion Documents

The following are available:

Chronic pain disorder medical treatment guidelines. Referenced version. Denver (CO): Colorado Division of Workers' Compensation; 2017 Nov 30. 237 p. Available from the Colorado Division of Workers' Compensation Web site .

Search strategy and study selection. Chronic pain disorder medical treatment guideline 2017 revision. Denver (CO): Colorado Division of Workers' Compensation; 2017. 4 p. Available from the Colorado Division of Workers' Compensation Web site .

Chronic pain disorder medical treatment guideline 2017. Evidence summary and tables. Denver (CO): Colorado Division of Workers' Compensation; 2017. 61 p. Available from the Colorado Division of Workers' Compensation Web site .

General literature search strategy for medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation. 1 p. Available from the Colorado Division of Workers' Compensation Web site .

Division of Workers' Compensation medical treatment guidelinesâ€methodology. Denver (CO): Colorado Division of Workers' Compensation. 10 p. Available from the Colorado Division of Workers' Compensation Web site .

In addition, related critiques are available from the Colorado Division of Workers' Compensation Web site . Assessment criteria for critiques are also available from the Colorado Division of Workers' Compensation Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 27, 2012. The information was verified by the guideline developer on December 28, 2012. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This summary was updated by ECRI Institute on July 3, 2014 following the U.S. Food and Drug Administration advisory on Epidural Corticosteroid Injection. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated by ECRI Institute on April 27, 2018. The updated information was verified by the guideline developer on April 30, 2018.

This NEATS assessment was completed by ECRI Institute on April 24, 2018. The information was verified by the guideline developer on April 30, 2018.

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